

# Creating a Drug Listing SPL Document – Human Prescription Drugs

Basic instructions for creating a  
technically valid listing SPL document  
for a Human Rx drug product.

Version 1.0

# Use SPL Starter Package

- Link to SPL Starter Package is located under the heading "Resources" on this web page:  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

\*\*\*You can also utilize other SPL authoring software solutions to create valid SPL documents. See this web page: <http://spl-work-group.wikispaces.com/Vendors>

NOTE: This is NOT an FDA endorsement for these software products.

# Accessing the Listing SPL Xforms

- Open listing SPL document Xforms file “SPLForm\_DrugListing.xhtml” (or equivalent in your SPL authoring software.)

# Selecting Document Type

## Document Information

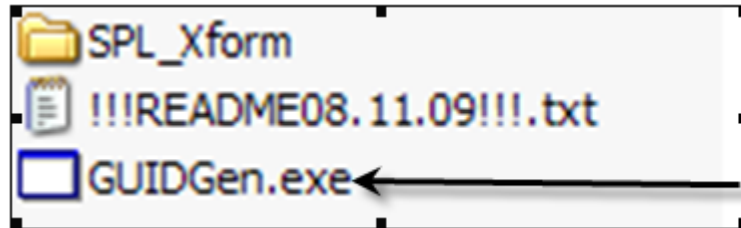
Type of document

HUMAN PRESCRIPTION DRUG LABEL



- Select document type appropriate for drug product from the drop-down menu.

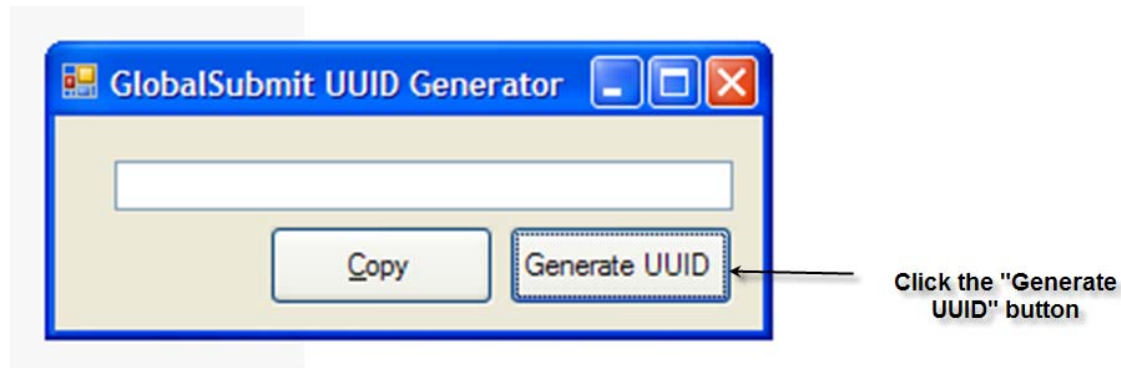
# Generating GUIDs for IDs



Use the **GUID** generator executable file  
or online version

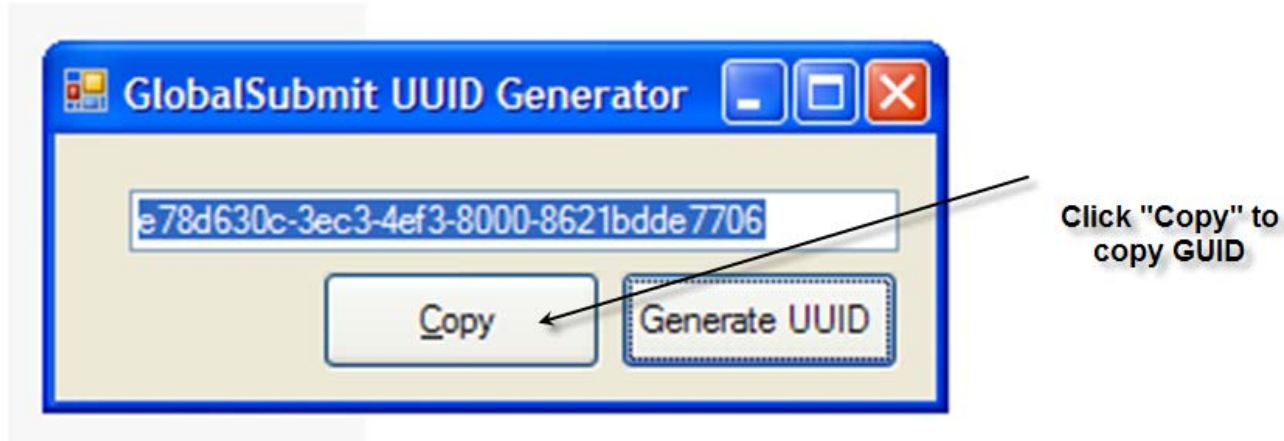
- Locate the Globally Unique Identifier (GUID) generator in the folder containing the SPL Xforms. GUIDs are also referred to as Universal Unique Identifiers (UUIDs)
- Double click executable file named “GUIDGen.exe.”
- If this program is incompatible with your PC, then search for an “online GUID generator” via your internet browser.

# Generating GUIDs for IDs cont...



- Generate a GUID by choosing the “Generate UUID” button (or equivalent in online GUID generator tool.)

# Generating GUIDs for IDs cont...



- Copy a GUID by choosing the “Copy” button (or equivalent in online GUID generator tool.)

# Adding a SPL Document ID

ID

c46d775b-d995-4bc7-b3ac-e979c8c157aa

- Paste GUID in “ID” field
- The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID).
- Hereafter, the “id root” will be referred to as “ID” or “document ID” in this eBook.



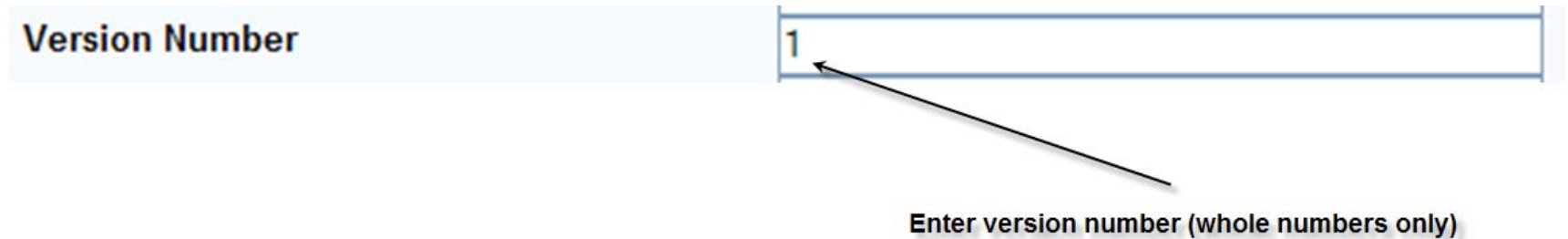
# Assigning a Set ID

Set ID

c2ad48a4-85ca-47b7-bb66-f260802e8c88

- Generate and copy another GUID using the GUID generator.
- Paste this GUID in the “Set ID” field.
- The setID root uniquely identifies a group of versions of an SPL file.

# Version Number



A form with a light blue header bar containing the text "Version Number". Below the header is a white input field with a blue border. The number "1" is entered in the field. A black arrow points from the text "Enter version number (whole numbers only)" below to the input field.

Version Number

1

Enter version number (whole numbers only)

- Enter a version number.
- The version number must be a **whole** number greater than zero.
- No spaces should be included before or after the version number.

# Entering a Document Date

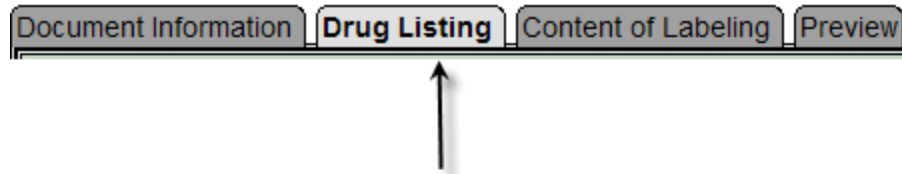
Effective Time	20090920
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Enter approximate submission date



- Enter a document date (Effective Time)
- Ensure that there are no spaces (created w/keyboard space bar) before or after date.
- The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format yyymmdd.

# Navigating to the Drug Listing Screen



Click the "Drug Listing" tab

- Now that you have entered the document tracking information, navigate to the drug listing screen by clicking the “Drug Listing” tab.


# Entering the Labeler's Name

Labeler	
Name	<input type="text" value="Acme Inc."/>

- Type in the name of the labeler.
- The labeler is the registrant or private label distributor (PLD) requesting the NDC Labeler Code or the registrant or PLD who is submitting an already assigned NDC Labeler Code.
- Ensure that the labeler name is the same as the name in the NDC Labeler Code SPL that has the labeler code which is the first segment of the NDC in this listing SPL.

# Labeler's DUNS Number

Labeler	
Name	Acme Inc.
DUNS Number	523521923



Enter DUNS Number for labeler.

- Type the DUNS Number for the labeler code owner's headquarters.
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number
- Ensure that the labeler DUNS Number is the same as the number in the NDC Labeler Code SPL which has the labeler code which is the first segment of the NDC in this listing SPL.


# Registrant Listing for PLD Name

Registrant	
Name	Johnson Pharm

- The registrant (owner/operator) of establishments (which manufactured the product) name is included **IF** the registrant is listing a drug made for a private label distributor.
- Otherwise, **DO NOT** complete this field in the listing SPL.
- Use the business name of registrant.

# Registrant Listing for PLD DUNS Number

Registrant	
Name	Johnson Pharm
DUNS number	995281221




Enter DUNS Number for registrant

- Type the DUNS Number for the registrant.
- **Only complete this field if you are the registrant listing on behalf of the PLD.**
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number



# Marking the Registrant As Confidential

Registrant	
Name	Johnson Pharm
DUNS number	995281221
Mark as Confidential	<input type="checkbox"/>



Marking the registrant as confidential

- Use checkbox if the registrant information is confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.

# Adding Establishments to Listing File

Establishment	
Name	Johnson Pharm

- The establishments are the entities involved in the manufacturing or processing the product.
- Enter one or more establishments.

# Entering DUNS Number for Establishment

Establishment	
Name	Johnson Pharm
DUNS number	952311231




Enter DUNS Number for establishment

- Type the DUNS Number for the establishment.
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/keyboard space bar) before or after DUNS Number

# Marking Establishment As Confidential

Establishment	
Name	Johnson Pharm
DUNS number	952311231
Mark as Confidential	<input type="checkbox"/>



Check here if the establishment information is confidential

- Check if the establishment information is confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.

# Type of Operation for Establishment

Type of operation

manufacture

Add Type of Operation

Delete Type of Operation

To include additional types of operation, click the "Add Type of Operation" button.

Use drop-down list to select appropriate type of operation

- Select a type(s) of operation performed at the establishment for this specific drug product.
- Click the “Add Type of Operation” button to add **additional** operations. If no additional operations, ignore this button.

# Additional Establishments



- To include additional drug establishments, click the “Add Establishment” button.
- To remove drug establishments, select “Delete Establishment”.

# Add Product Data Elements Section



- Each drug listing SPL for a human prescription drug product should have at least one product data elements section.
- Click the “Add Product” button

# Product Data Elements Section ID

ID	e9612806-2469-4113-b5d2-dca534e4e145
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Add an ID for product data element section

- Each section has an ID (GUID)
- Add the ID for product data element section.




# Section's Effective Time (Date)

Effective Time	20090626
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- Enter a time stamp (effective time) for the section
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference for the section.
- The date includes the year, month and day using the format `yyyymmdd`.

# Dosage Form

Product Information	
Dosage Form	CREAM 

- The dosage form of the drug product is the physical form as packaged.
- Select the appropriate dosage form from the drop down list.

# Proprietary Name

## Product Information

Proprietary Name

Betamethasone Dipropionate

- The proprietary name is the brand or trade name **without additional qualifiers** such as “extra strength” or “XR”.
- For drug products which do not have a proprietary name, include the non proprietary name without additional qualifiers as the proprietary name.
- Enter the proprietary name. If there is a suffix, leave a space after the name.

# Proprietary Name Suffix

Proprietary Name Suffix

- The proprietary name suffix is **the additional qualifiers** added to the proprietary name.
- If there are no additional qualifiers, then leave suffix field empty.

# Non-proprietary Name

Non-Proprietary Name

betamethasone dipropionate

- Enter name(s) of **active ingredient(s)** in the non-proprietary name field in product data elements section.
- **DO NOT** include “USP” in the non-proprietary field in the product data elements section

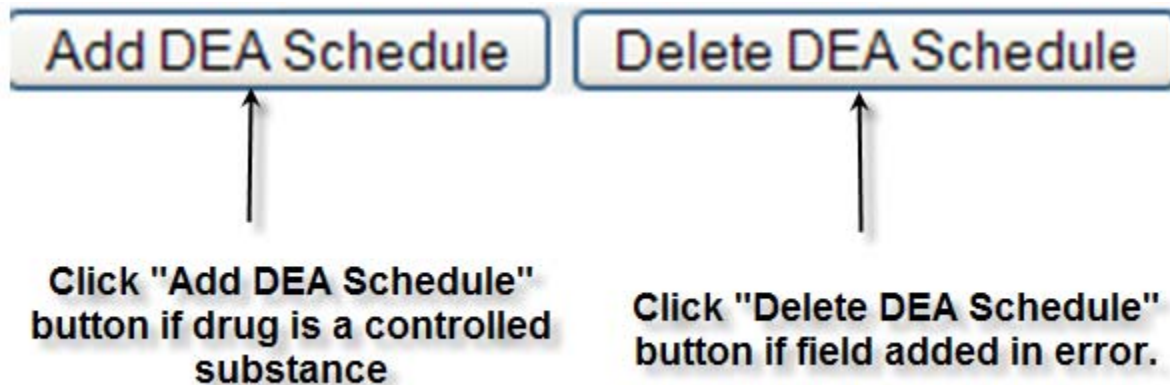
# NDC Product Code

NDC Product Code

11445-123

- The NDC Product Code is the NDC Labeler Code and the product code segment of the NDC separated by a hyphen.
- Enter the NDC Product Code

# DEA Schedule



- Click “Add DEA Schedule” button, if applicable.
- From the drop-down menu, select the appropriate DEA schedule for the drug product

# Route of Administration

Route of Administration	TOPICAL	▼
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- Click “Add Route of Administration” button
- Select the route of administration applicable for drug product.
- Click “Add Route of Administration” button again to add more routes, if applicable.



# Active Ingredients



- Click “Add Active Ingredient” button if there are active ingredients.
- Select “Delete Active Ingredient” button if chosen in error.
- Select “Add Active Ingredient” button for each active ingredient.


# Active Ingredient Name

Active Ingredient	
Name	betamethasone dipropionate

- Enter active ingredient name (preferred name) without additional qualifiers such as “USP,” “NF,” etc...

# Adding UNII for Active Ingredient

Active Ingredient	
Name	betamethasone dipropionate
Unique Ingredient Identifier (UNII)	826Y60901U




Enter UNII for active ingredient

- Enter the preferred name and Unique Ingredient Identifier (UNII) for the active ingredient.
- Select UNII from list accessible via this web page:  
<http://www.fda.gov/ForIndustry/DataStandards/Structure dProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov).

# Strength of Active Ingredient

Active Ingredient			
Name	betamethasone dipropionate		
Unique Ingredient Identifier (UNII)	826Y60901U		
Strength	0.64	mg	in 1 g

Enter strength as ratio  
Use metric units



- Strength is represented as a ratio.
- The numerator and denominator have a value and a unit.
- The value is the amount of ingredient for a dose (usually a whole number) based on either the active ingredient or active moiety.
- Enter the value and select the appropriate unit for the numerator and denominator for the strength.

# Active Moiety Name

## Active Moiety

Name

betamethasone

- There are one or more active moieties for each active ingredient.

# Entering UNII for Active Moiety


Active Moiety	
Name	betamethasone
Unique Ingredient Identifier (UNII)	9842X06Q6M
<input type="button" value="Add Active Moiety"/> <input type="button" value="Delete Active Moiety"/>	

Enter UNII for active moiety

- Enter the preferred name and UNII for the active moiety for the active ingredient.
- Select UNII from list accessible via this web page:  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov).
- Click “Add Active Moiety” button to include additional active moieties.

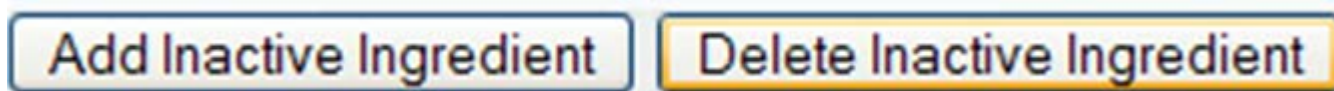
# Basis of Strength

Basis of Strength

Active Ingredient 

- Select if the active ingredient or active moiety is used as the basis of the strength of the drug.

# Adding Inactive Ingredients



- Click the “Add Inactive Ingredient” button to add inactive ingredient name(s) and UNII(s), if applicable.




# Inactive Ingredients

Inactive Ingredient	
Name	Water

- Enter inactive ingredient name (preferred name)

# Adding UNII for Inactive Ingredient

Inactive Ingredient	
Name	Water
Unique Ingredient Identifier (UNII)	059QF0KO0R



**Enter the UNII for the inactive ingredient.**

- Enter the preferred name and Unique Ingredient Identifier (UNII) for the inactive ingredient.
- Select UNII from list accessible via this web page:  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov).

# Marking the Inactive Ingredient as Confidential

Inactive Ingredient	
Name	Water
Unique Ingredient Identifier (UNII)	059QF0KO0R
Mark as Confidential	<input type="checkbox"/>



Check the box if the inactive ingredient is confidential

- Check if the inactive ingredient is to be considered as confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.

# Adding the Strength for an Inactive Ingredient.




- To add the strength for an inactive ingredient, click the “Add Strength” button.
- To remove the strength of an inactive ingredient, click the “Delete Strength” button.
- If applicable, follow the instructions for including strength for an active ingredient.

# Adding a Flavor



- Flavors are described as product distinctive characteristics rather than ingredients.
- **If applicable**, add a flavor by clicking the “Add Flavor” button.
- To remove a flavor, click the “Delete Flavor” button.


# Selecting a Flavor

Flavor	
Name	COFFEE 

- Select a flavor from the flavor “Name” drop-down menu.
- If flavor and/or original text are **not needed**, **delete the field**.

# Adding Flavor Original Text

Flavor	
Name	COFFEE
Original Text	Coffee Flavor



Enter free text to include additional description of flavor.

- Enter additional description of the flavor into the original text field.

# Adding a Color



- **If applicable**, to add a color, click the “Add Color” button.
- To remove a color, click the “Delete Color” button.
- More than one color can be added for each product, if applicable.



# Selecting a Color



A screenshot of a web form. On the left, there is a light blue rectangular label with the word "Color" in a dark blue font. To the right of this label is a white rectangular input field with a thin blue border. Inside the input field, the word "blue" is written in a dark blue font. To the right of the input field is a small blue square button with a white downward-pointing chevron (v) inside it, indicating a dropdown menu.

- Select a color from the “Color” drop-down menu.
- If applicable

# Adding Original Text for Color

Color	blue
Original Text	Sky Blue



Type as free text additional description for color.

- Enter additional description of the color into the original text field.
- If color and/or original text are not needed, delete the field.
- If applicable

# Adding Imprint Information



- Click “Add Imprint” button for describing **solid oral dosage form** product characteristics.
- **If not applicable**, select the “Delete Imprint” button if “Add Imprint” button is chosen in error.

# Score



The image shows a web form element. On the left, there is a light gray rectangular label with the text "Score" in a bold, black, sans-serif font. To the right of this label is a dropdown menu. The dropdown menu has a blue border and contains the text "Two even pieces" in a black, sans-serif font. To the right of the text is a small blue square button with a white downward-pointing chevron. A black arrow points from the text "Select appropriate score value." below to the dropdown menu.

Select appropriate score value.

- If applicable
- Select the appropriate score
  - no score = 1
  - scoring with two equal pieces = 2,
  - scoring with three equal pieces = 3,
  - scoring with four equal pieces = 4,
  - other = nullFlavor = OTH).


# Selecting a Shape



- Select the appropriate shape from drop-down list.
- If applicable

# Adding Original Text for Shape

Shape	OVAL
Original Text	Capsule



Enter additional descriptive information for shape.

- Enter additional description of the shape into the original text field.

# Entering Imprint Information

Imprint Code

3:hp;x

- **IF APPLICABLE**, Enter the imprint code by beginning on either side or part of the dosage form.
- Start at the top left and progress as one would normally read a book.
- **Enter a semicolon to show separation between words or line divisions.**
- If there is no imprint code, **leave the field blank.**

# Entering the Size

Size

19

- Size is represented by the longest single dimension of the solid dosage form as a physical quantity in the dimension of length (e.g., 19 mm).
- Enter the value rounded to the nearest whole number in the size field
- If applicable




# Entering the Size Unit

Size Unit	mm
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- Enter mm in the size unit field.
- If applicable

# Marketing Status of Product

Marketing Date	
Product Status	Active 

- The marketing status describes the activity of the product.
- If the product is on the market, choose “Active.”
- If the product is no longer on the market, choose “Completed” as the marketing status.

# Entering Marketing Start Date for a Currently Marketed Product

Marketing Date	
Product Status	Active 
Start Marketing Date	20080313

- If product is on the market, enter the approximate start marketing date using the YYYYMMDD format.

# Entering Marketing End Date for a Discontinued Product

Marketing Date	
Product Status	Completed
Start Marketing Date	19830313
End Marketing Date	20091003

Enter approximate end marketing date if delisting the product

- If marketing of product is discontinued, select “Completed” from the Product Status drop-down menu.
- Then enter the approximate end marketing date using the YYYYMMDD format in the “End Marketing Date” field.

# Marketing Category – Application

## Marketing Category

Marketing Category

NDA



- Select the appropriate marketing category for a product from the drop-down menu.

# Application Number

Add Application or citation number

Delete Application or citation number

- To add an application number, click the “Add Application or citation number” button.

# Entering the Application Number

Marketing Category	
Marketing Category	NDA
Application or citation number	NDA013111

Enter application number

- Enter application number (six digits) with marketing category as a prefix

# Adding the Application Number Code System

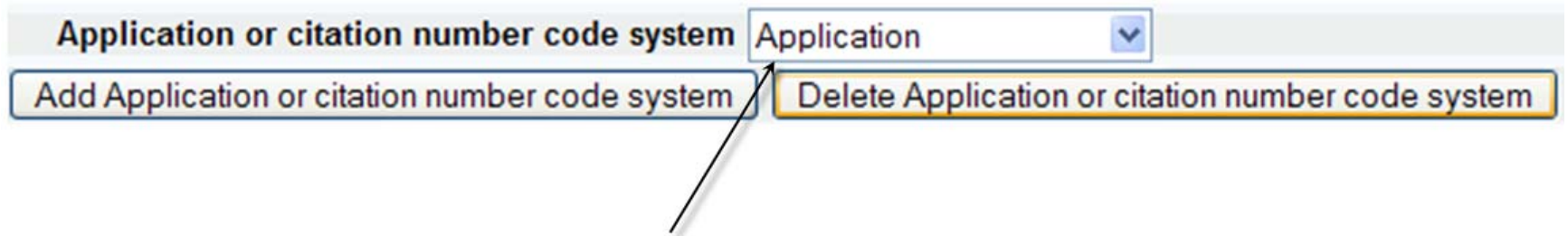
Add Application or citation number code system

Delete Application or citation number code system

- To add the application number code system, select the “Add Application or citation number code system” button.



# Selecting the Code System




The screenshot shows a web form with a light blue header bar. The header bar contains the text "Application or citation number code system" followed by a dropdown menu showing "Application" with a blue downward arrow. Below the header bar, there are two buttons: "Add Application or citation number code system" on the left and "Delete Application or citation number code system" on the right. A black arrow points from the text "Select 'Application' from drop-down menu" below to the dropdown menu.

Select "Application" from drop-down menu

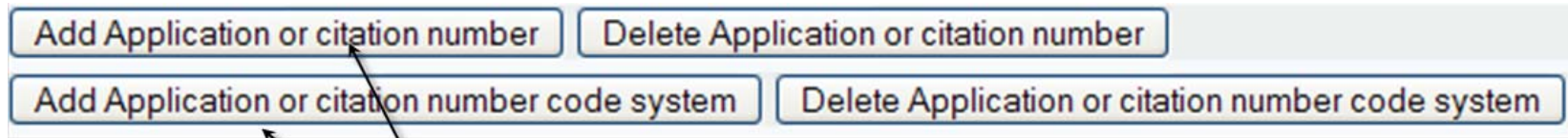
- Select “Application” as the code system for human Rx drug products with application numbers.

# Marketing Category – No Application Number

Marketing Category	
Marketing Category	<input type="text" value="unapproved drug other"/> 

- Select the appropriate marketing category for a product from the drop-down menu.

# Marketing Category – No Application Number

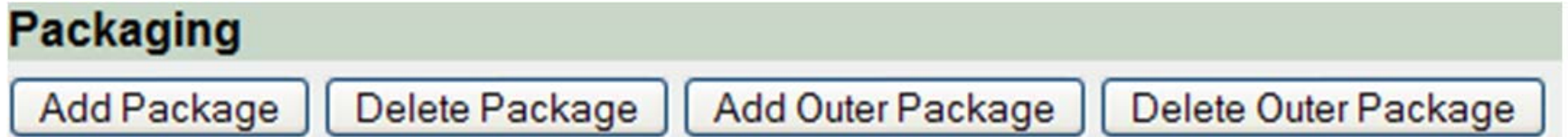


Add Application or citation number	Delete Application or citation number
Add Application or citation number code system	Delete Application or citation number code system

IF NO APPLICATION NUMBER  
DO NOT CLICK "Add Application or citation number" OR  
"Add Application or citation number code system"

- IF NO APPLICATION NUMBER **DO NOT CLICK**
  - “Add Application or citation number” button, OR
  - “Add Application or citation number code system” button

# Packaging



- Click on the “Add Package” button to add a package configuration.

# Entering NDC Package Code

The diagram illustrates the structure of the NDC Package Code. It features a header bar labeled "Packaging" in a light green box. Below this, a light gray box contains the label "NDC Package Code (10 digit)". To the right of this label is a white input field containing the code "11145-123-01". Dotted arrows point from the input field to two explanatory text blocks. The first block, "NDC Labeler Code (1st segment) in this file should match the labeler code in the NDC Labeler Code SPL file.", has an arrow pointing to the first five digits "11145". The second block, "NDC Product Code (1st two segments should match NDC Product Code entered earlier in this file.", has an arrow pointing to the first six characters "11145-123".

Packaging

NDC Package Code (10 digit)

11145-123-01

NDC Labeler Code (1st segment) in this file should match the labeler code in the NDC Labeler Code SPL file.

NDC Product Code (1st two segments should match NDC Product Code entered earlier in this file.

- Enter the 10 character NDC Package Code. The NDC Package Code is the NDC Product Code and the package segment of the NDC separated by a hyphen.
- NDC Labeler Code (1<sup>st</sup> segment) should match labeler code in the NDC Labeler Code SPL file.
- NDC Product Code (1<sup>st</sup> two segments) should match the NDC Product Code entered in the NDC Product Code field of same file.
- **DO NOT** use asterisks in package code field.

# Entering Quantity for Packaging Description

Quantity	40	GRAM	▼
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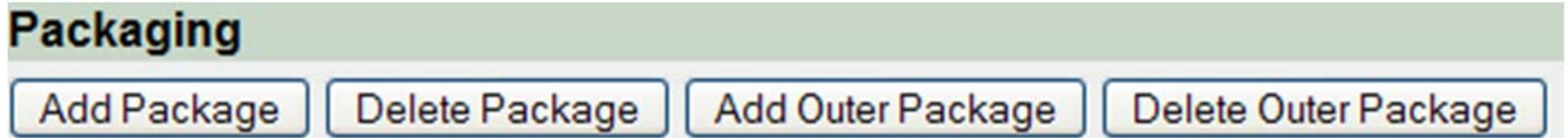
- Enter the quantity in the first field and then select the appropriate unit.
- The unit is the same as the denominator unit for the ingredient strength.
- The UCUM will be used in the strength description and the term will be used in the package description.
- Example:
  - **Strength:** “g” (“g” is the UCUM for “gram”)
  - **Package description:** “GRAM.”

# Adding Package Type

Package Type  

- Select the appropriate package type.

# Adding Outer Package



- Click on “Add Outer Package” button to add an outer retail package configuration and repeat the previous steps.



# Example of Multi-Level Packaging

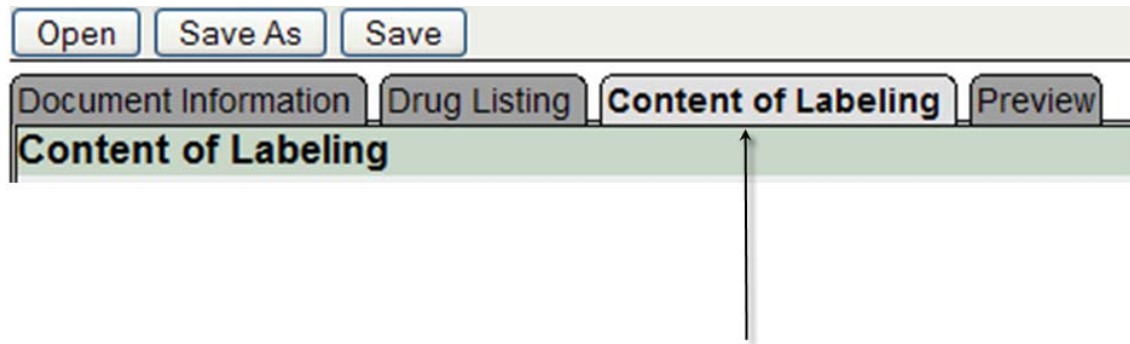
Packaging		
NDC Package Code (10 digit)	11445-123-01	
Quantity	40	GRAM
Package Type	TUBE	
NDC Package Code (10 digit)	11445-123-02	
Quantity	1	TUBE
Package Type	CARTON	

Inner level Packaging

Outer Level Packaging

- Note:
  - See above graphic for example of two levels of packaging with different NDC package codes (3-segment NDC)
  - If there is only one NDC for a multi-level packaged product, include the NDC on the outer level.

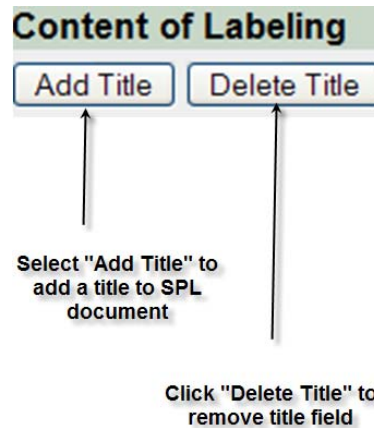
# Content of Labeling for Listing SPL Document



Click the "Content of Labeling" tab to navigate to the content of labeling section of listing SPL Xforms

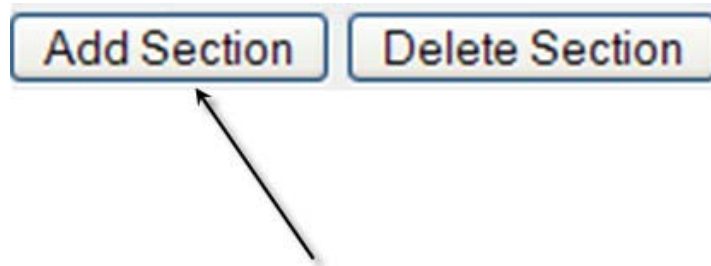
- Click the “Content of Labeling” tab to navigate to the content of labeling view of SPL Xforms.

# Adding SPL Document Title for Listing SPL Document



- Click on the “Add title” button.
- Enter the title of the label.
- If there are highlights (PLR format), then the title for the SPL file includes the text string (without quotation marks): “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”

# Add Section



Add at least one content of labeling section

- Click the “Add Section” to add the section.

# Choose Section Header

Section	DESCRIPTION SECTION	▼
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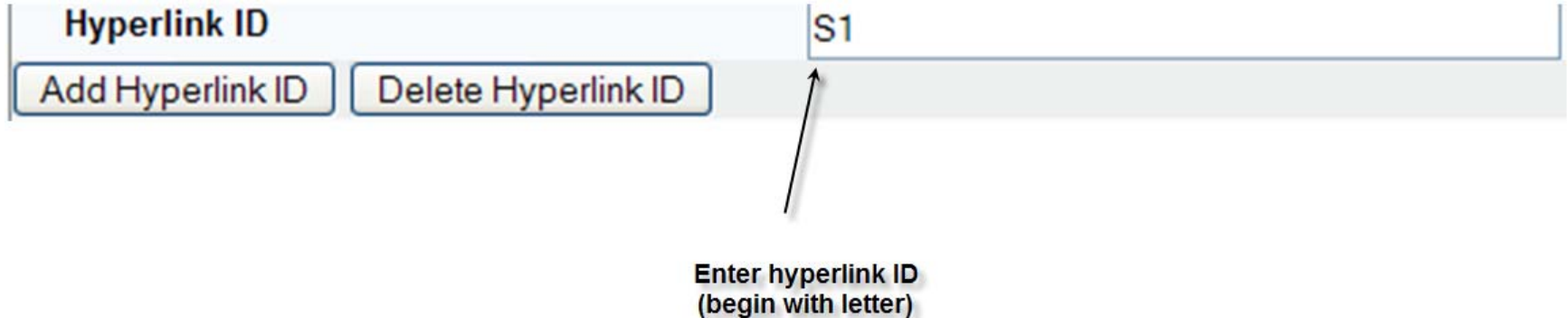
- Choose applicable section header from drop-down menu.

# Hyperlink ID



- Click “Add Hyperlink ID” button if cross references are needed.
- If no cross reference to a section is necessary, do not click “Add Hyperlink ID” button.

# Enter Hyperlink ID



The image shows a user interface for managing hyperlinks. At the top, there is a light blue header bar with the text "Hyperlink ID". Below this header, there are two buttons: "Add Hyperlink ID" and "Delete Hyperlink ID". To the right of these buttons is a text input field containing the text "S1". An arrow points from the text "Enter hyperlink ID (begin with letter)" below the buttons to the text input field.

Hyperlink ID

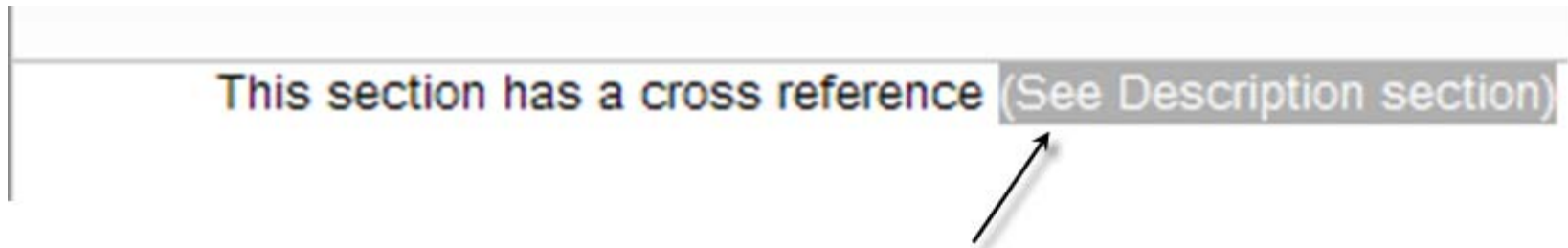
Add Hyperlink ID Delete Hyperlink ID

S1

Enter hyperlink ID  
(begin with letter)

- Enter hyperlink ID in the field
- Begin hyperlink ID with a letter

# Adding a Cross Reference



Select text to be used as cross reference link name

- To add a cross reference in a section, enter text for section
- Add cross reference link name
- Select the text to be used as a cross reference link name.

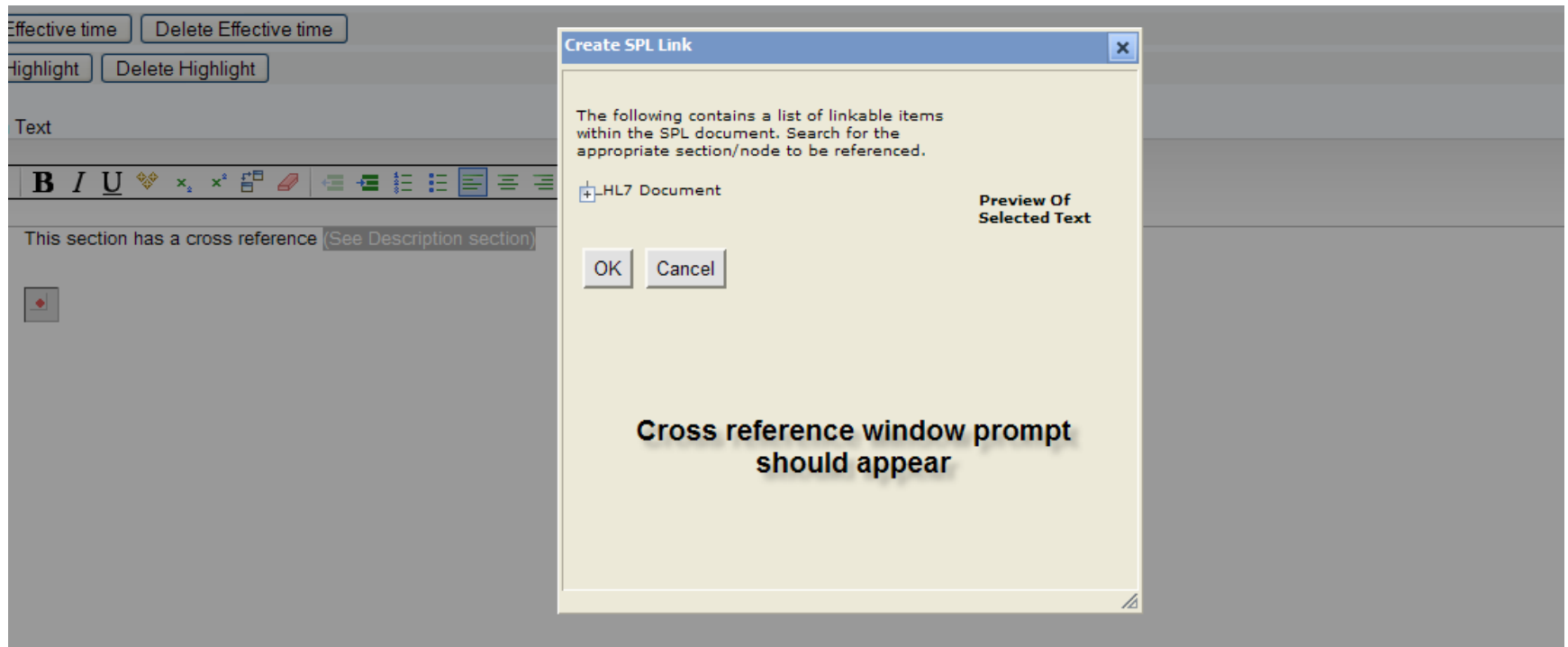


# Adding a Cross Reference cont...

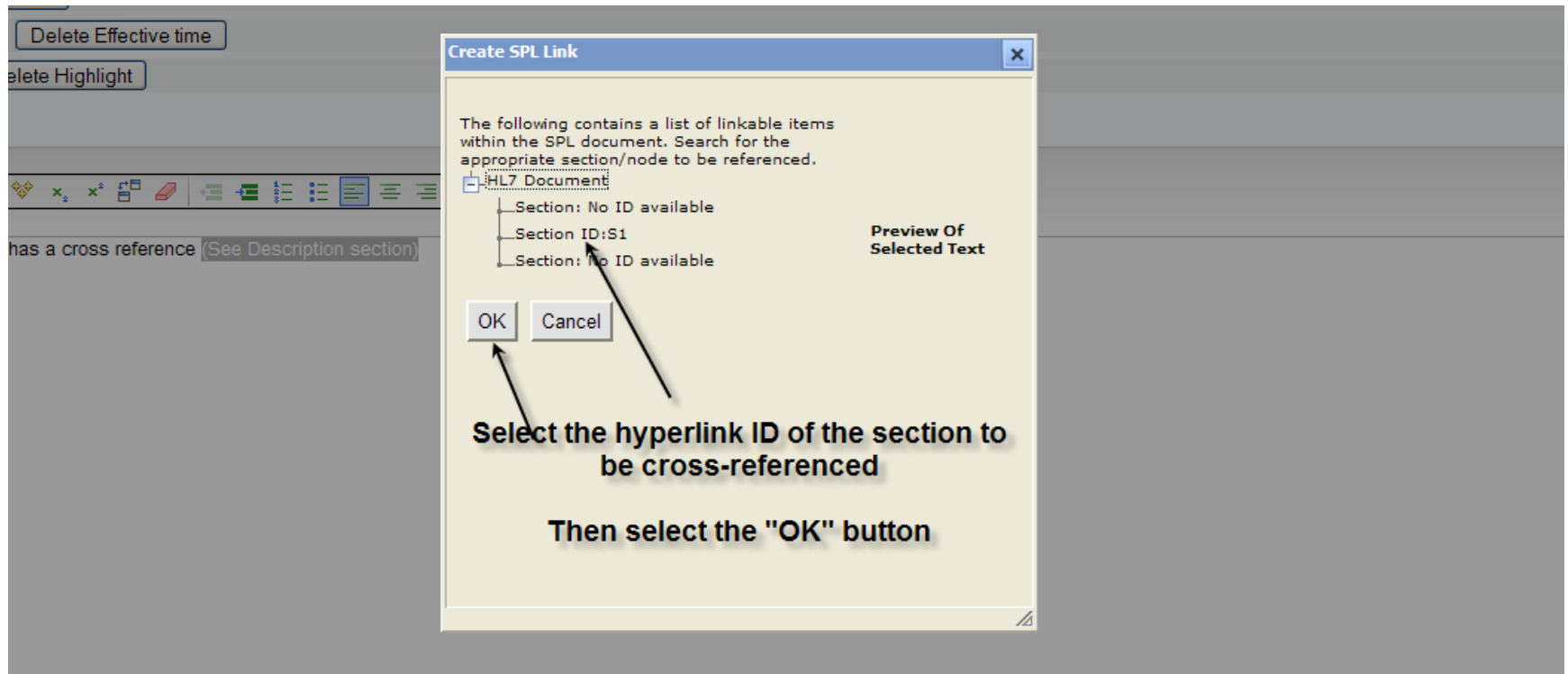


- Click the link icon in the “widgets” toolbar

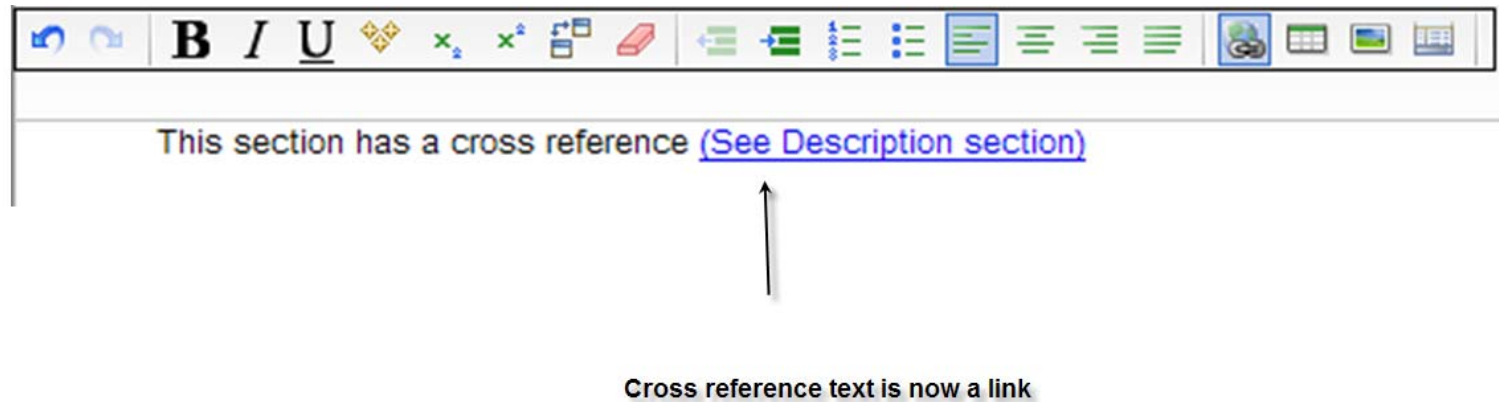
# Cross Reference Window Prompt



# Selecting the Section to be Cross-Referenced



# Section is Cross Referenced



- The cross reference text should now be a hyperlink
- Link should be active when viewing SPL using SPL stylesheet (Inactive from SPL Xforms)

# Enter Section ID

ID

62675ee0-e6f7-4488-8947-39e1d57fbb04

- Enter a GUID for the section ID.

# Adding Section Title



- Enter a section title, if necessary.
- If no section title, do not click “Add Title.”
- Use “Delete Title” if “Add Title” is selected in error.

# Section's Effective Time (Date)

Effective Time	20090626
----------------	----------

- Enter a time stamp (effective time) for the content of labeling section
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference for the section.
- The date includes the year, month and day using the format `yyyymmdd`.

# Highlights Feature



- If labeling is in the Physician's Labeling Rule (PLR) format, then click the "Add Highlight" button to add highlights text.

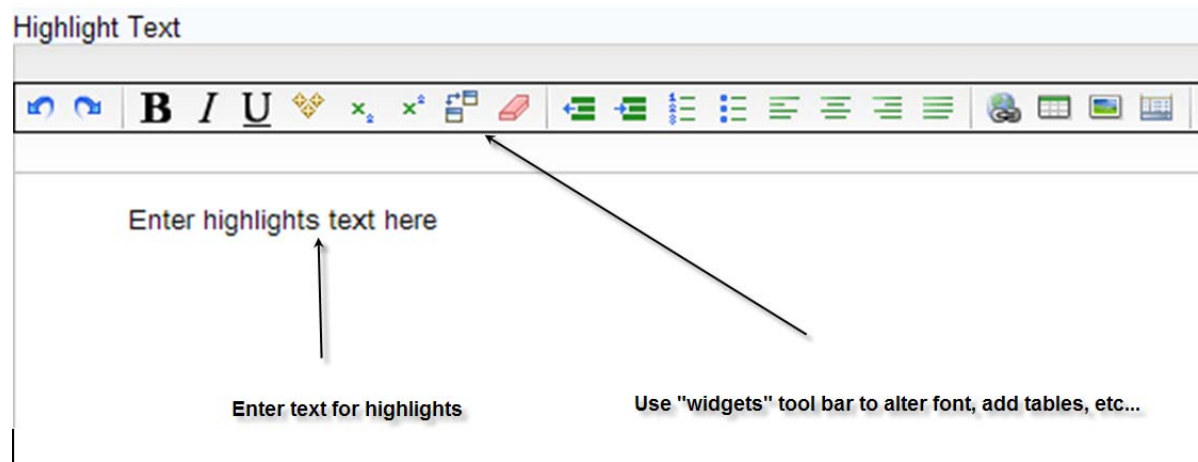


# Accessing Highlights Text Field



- Click “Edit” button to access the highlights text field.

# Entering Highlights Text



- Enter text from a section of the content of labeling
- Type or copy/paste text into section field.
- Use “widgets” to alter the font (bold, italics), etc...

# Saving the Highlights Text



- Click the “Save” button to save the highlights text just entered.

# Entering Section Text



Select "Edit" button to  
display section text field.

- Click the “Edit” button to display the section text field.

# Entering Text and Using “Widgets”



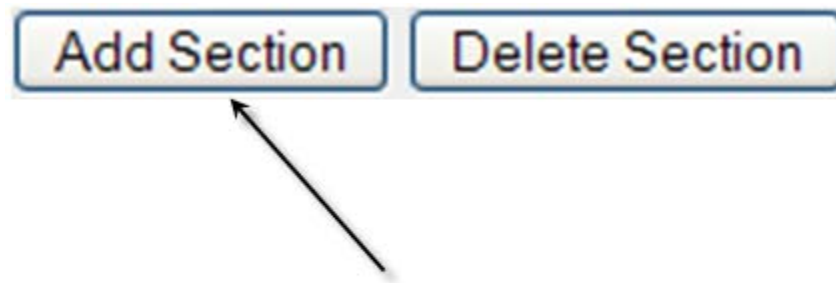
- Enter text from a section of the content of labeling
- Type or copy/paste text into section field.
- Use “widgets” to alter the font (bold, italics), etc...

# Saving the Section



- Click the “Save” button to save the section text just entered.

# Adding More Content of Labeling Sections



Click "Add Section" button to add a section.

- Follow the instructions in the previous pages related to content of labeling to create another section.
- Continue to add sections until each section or subsection in the content of labeling is represented in a separate SPL content of labeling section or sub-section.

# Adverse Reactions Section (PLR Format Only)

- An excerpt in the adverse reactions section (34084-4) includes the statement "to report suspected adverse reactions" and "1-800-FDA-1088" (different telephone numbers for documents of type 53404-0 – "Vaccine Label").
- For PLR format labels



# Adding Sub-sections



- Click “Add Sub-Section” button to add a sub-section, if applicable.

# Creating the Sub-Section

The screenshot shows a web form for creating a sub-section. It includes fields for 'Section ID' and 'Title', a 'Sub-section Text' area with a rich text editor, and buttons for 'Add Title' and 'Delete Title'. Callouts provide instructions on how to use these fields and buttons.

Section ID: MECHANISM OF ACTION SECTION  
0f5b5d46-7ec6-440b-abd0-73c232292e7a

Title: Mechanism of Action

Buttons: Add Title, Delete Title

Sub-section Text

Enter section text here

Callouts:

- Add a section header and ID
- Add a subsection title
- Add "clicking" subsection's "Edit" button, enter text for subsection and then select the "Save" button

- Follow steps used to create the content of labeling section, except this time, create a subsection.
- See graphic above for more details.

# Principal Display Panel Section

Section	PACKAGE LABEL.PRINCIPAL DISPLAY PANEL	▼
---------	---------------------------------------	---

- Add a section (not sub-section.)
- Choose Package.Label Principal Display Panel section header from “Section” drop-down menu.
- Listing SPL document for a human Rx drug product **should** have a “Package Label.Principal Display Panel” section header.
- Include image of carton/container label in this section.

# Referencing the Images Using “Add Media” Button

**Content of Labeling**

Add Title Delete Title

Section PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Add Hyperlink ID Delete Hyperlink ID

ID 276c2bdb-411e-4373-9766-dae2da1a0c5a

Add Title Delete Title

Add Effective time Delete Effective time

Add Highlight Delete Highlight

Section Text

Place holder text

Edit

**Observation Media**

Add Media Delete Media

Add Sub-Section Delete Sub-Section

Add Section Delete Section

Click "Add Media" button

# Entering ID, Descriptive Text & File Name

1. Enter an ID (e.g. "MM1" or "MM2" - each image ID should be unique)
2. Add descriptive text for image
3. Enter image file name

Section Text

Place holder text

Edit

## Observation Media

ID	MM1
Descriptive Text	image of carton label
File Name	carton.jpg

# Selecting Location of Image

Section Text

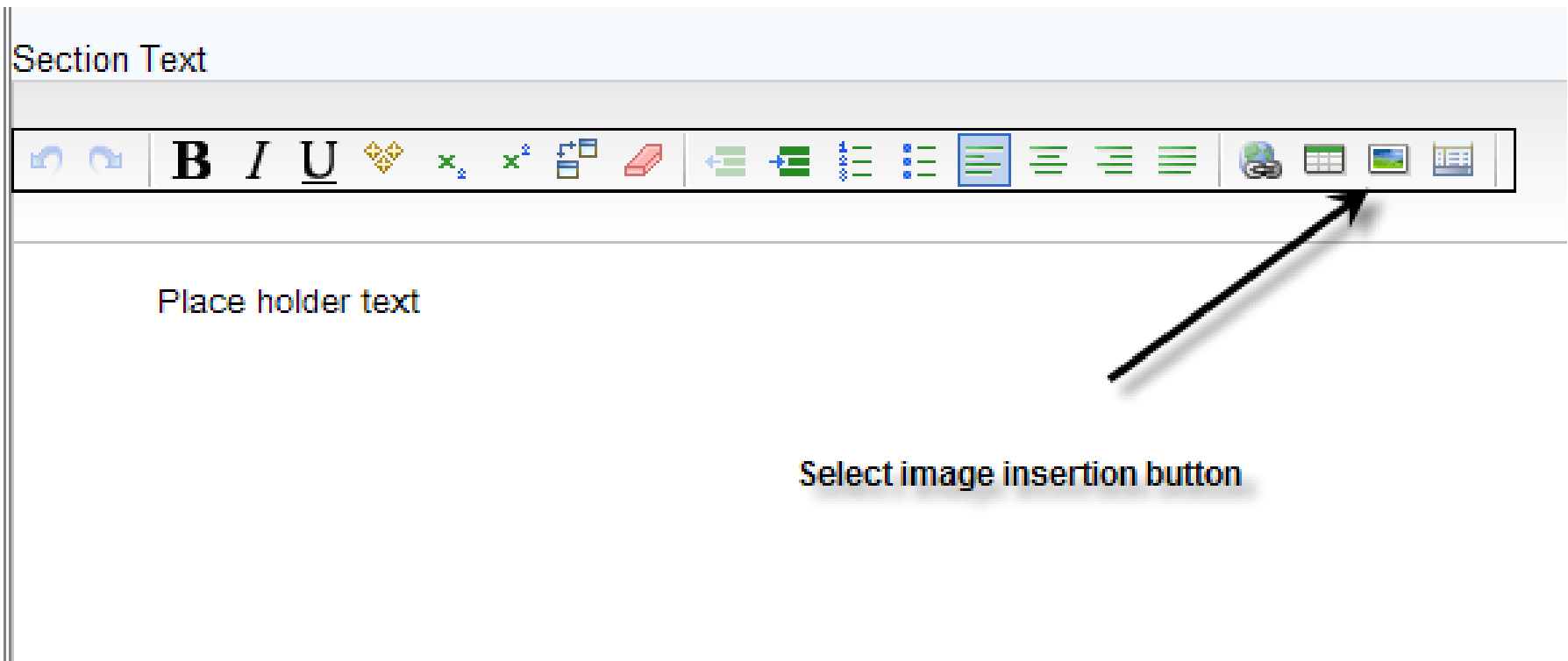


Place holder text

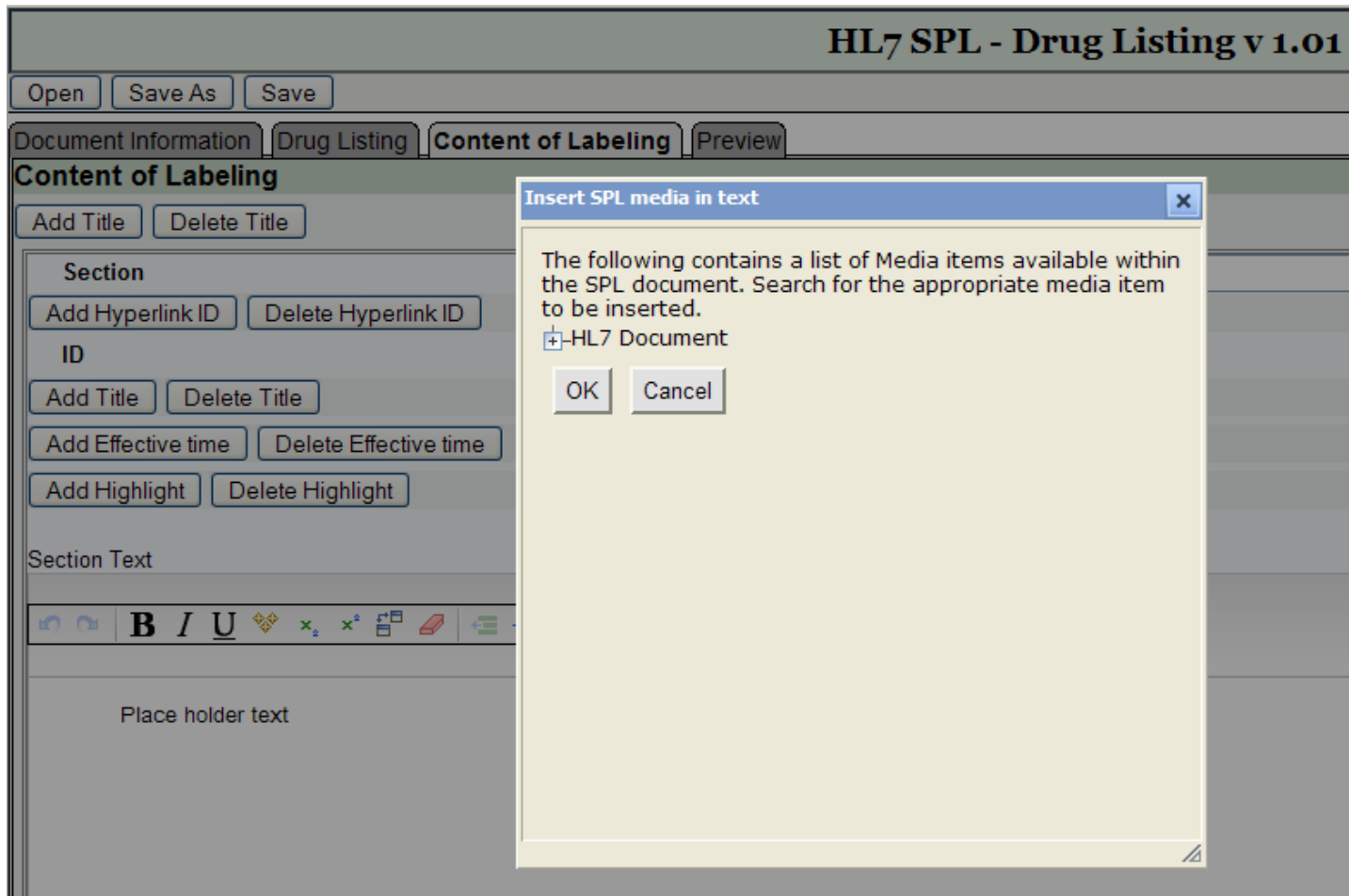


Place the computer cursor in the location where image should appear

# Selecting Image Insertion Button

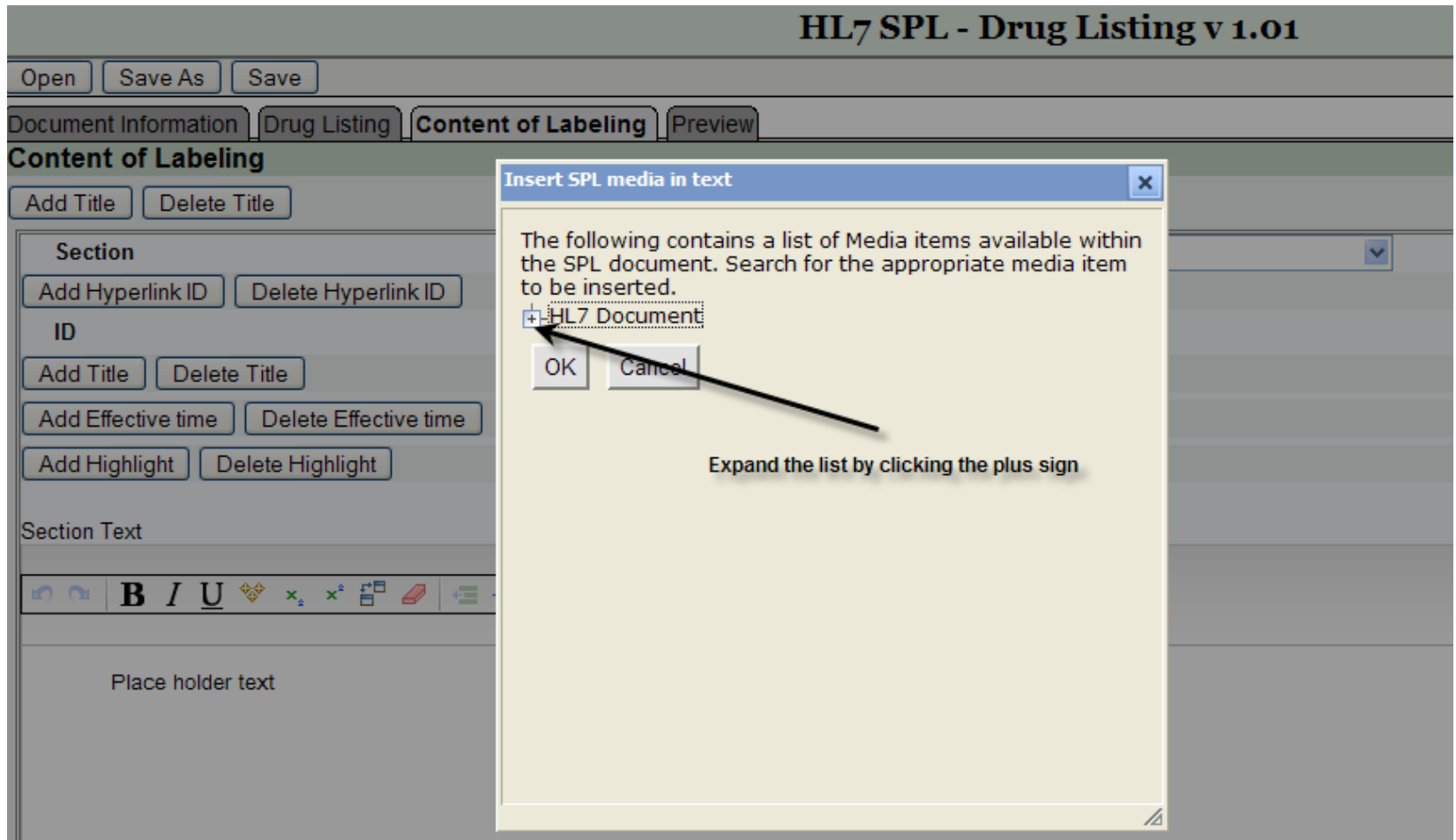


# Insert Media Prompt Box

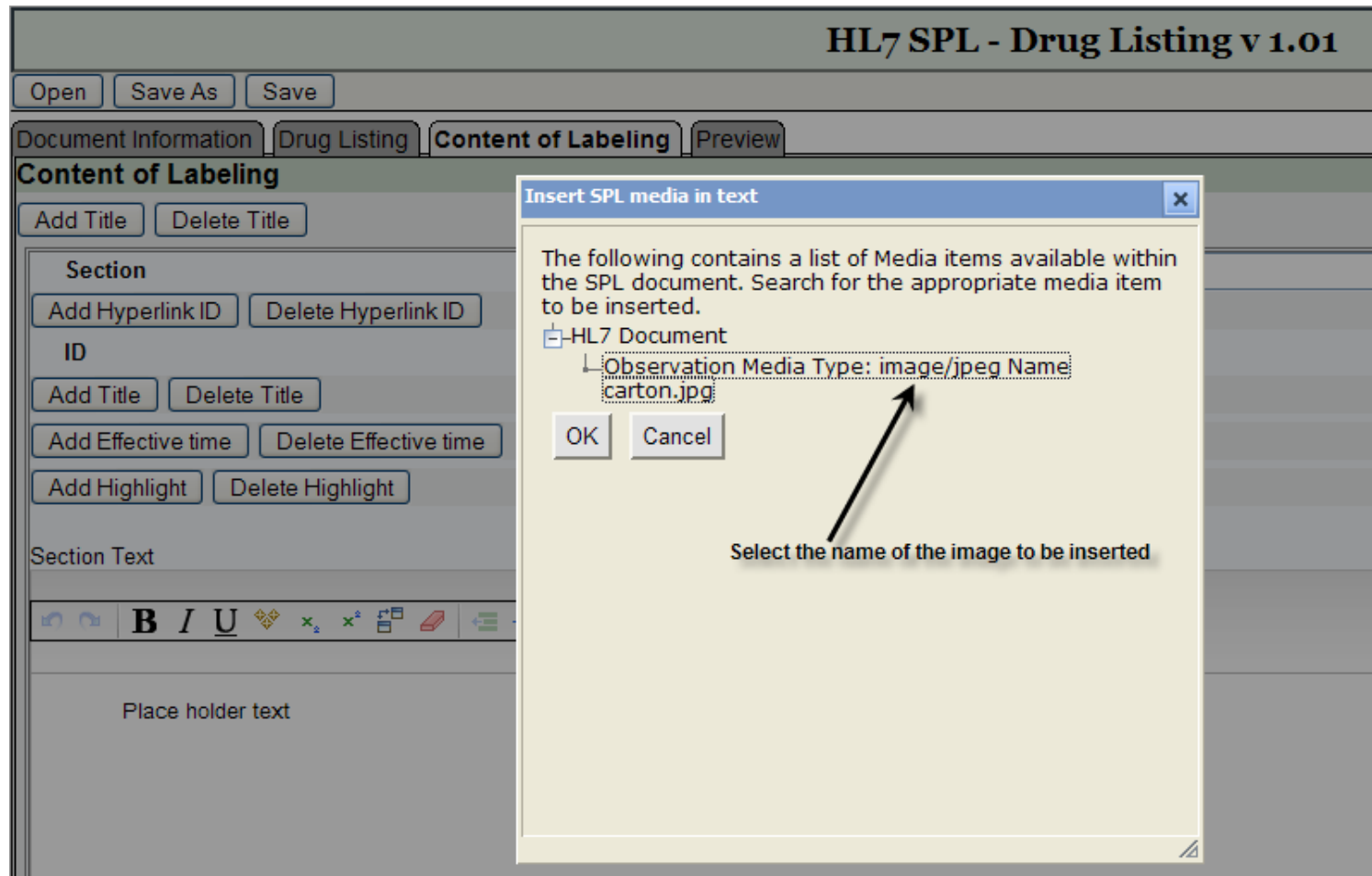




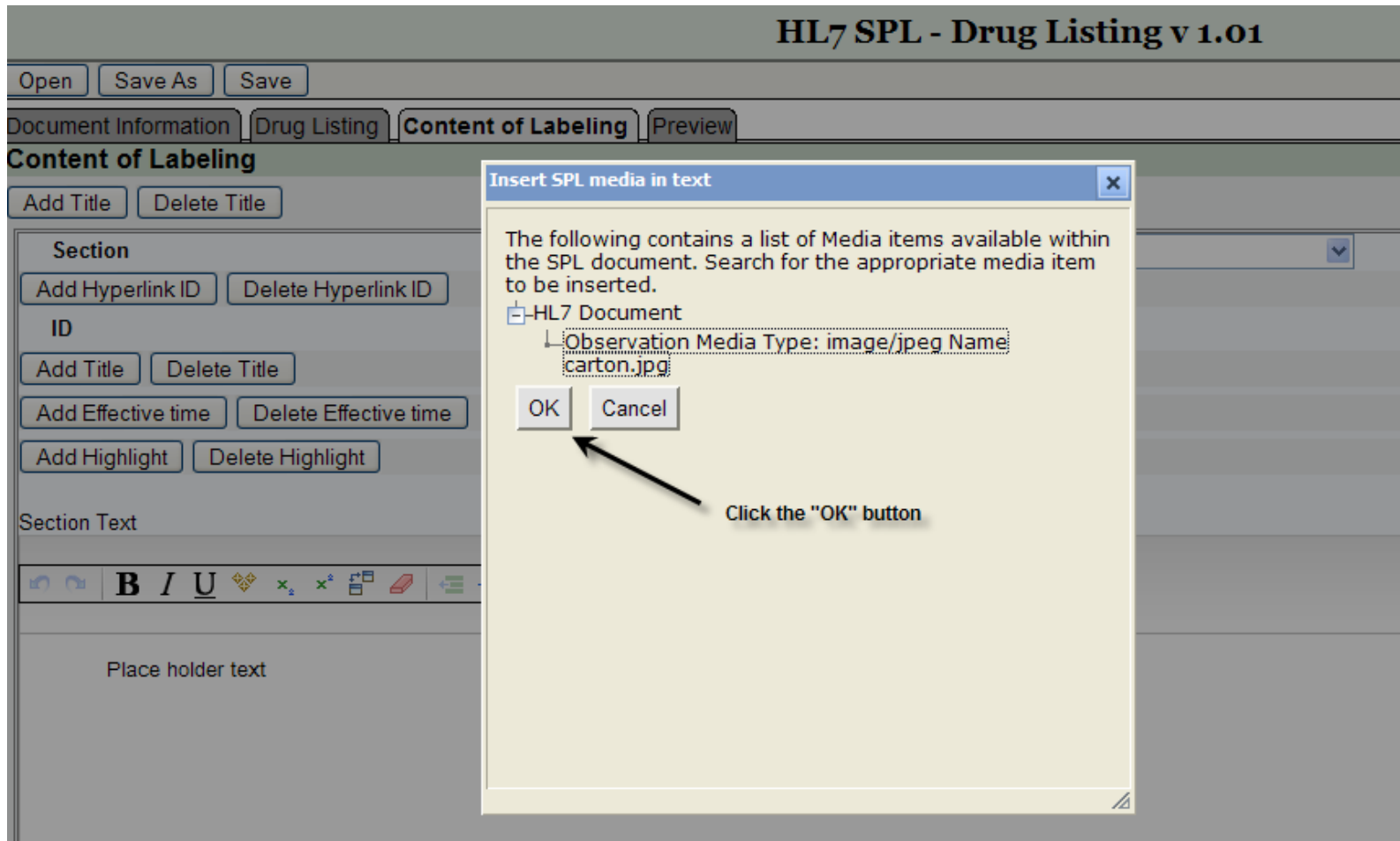
# Expanding Image List



# Selecting Image to Insert

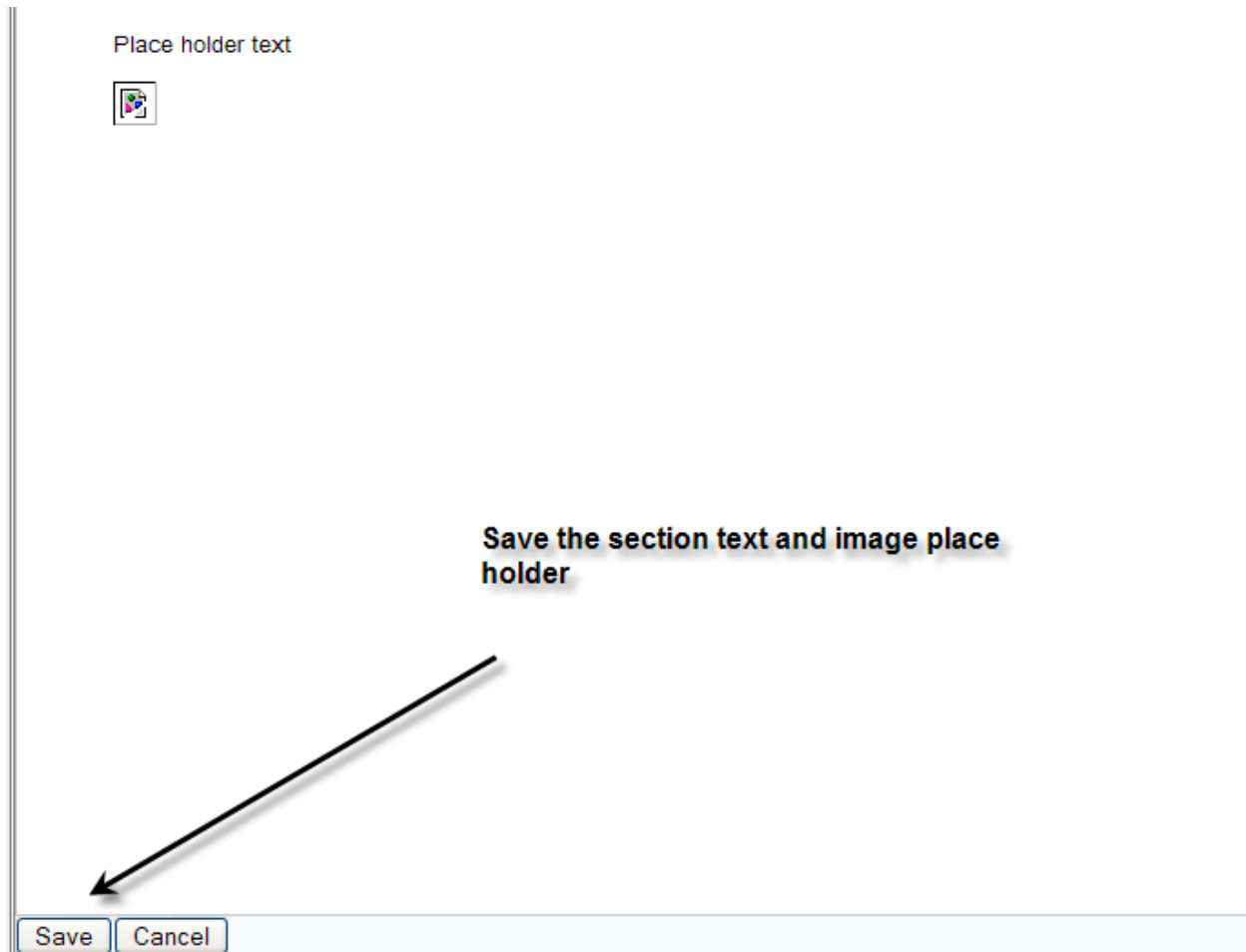


# Finish Image Selection





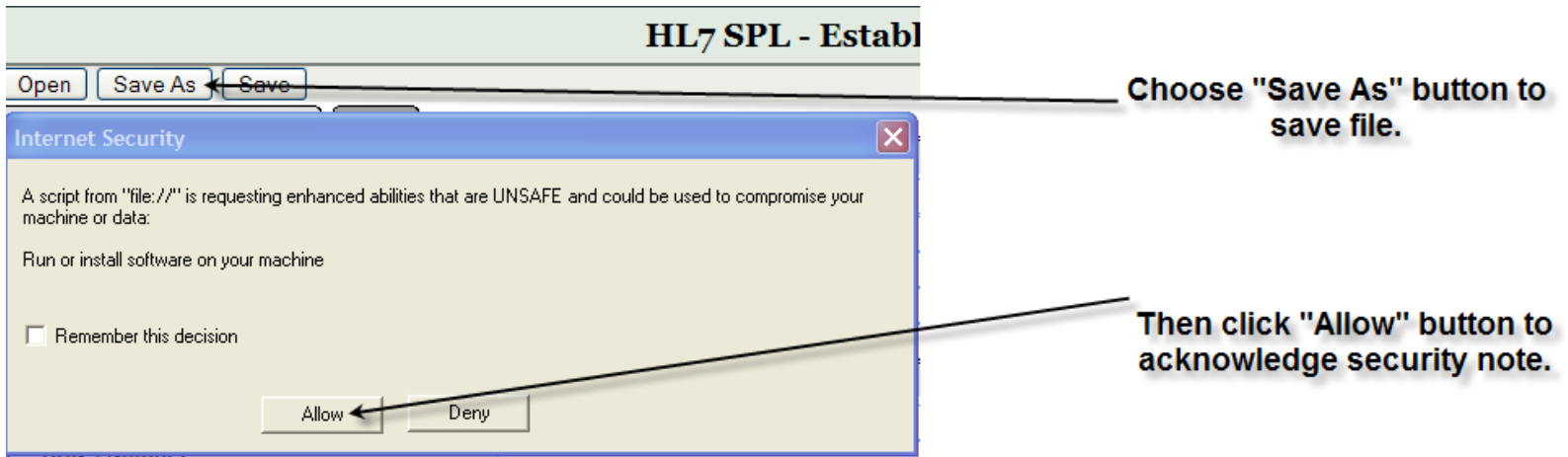
# Saving Section w/Image



# Image Notes

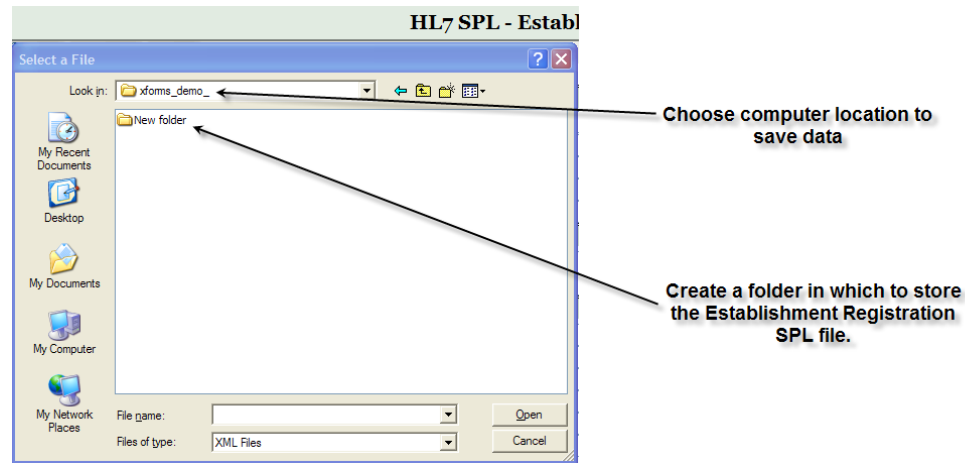
- Image should be viewable in window without scrolling.
- Size of image file should be under **1 MB**.

# Saving the File



- When saving the SPL file for the first time, select the “Save As” button.
- Then select the “Allow” button to continue saving.
- You can check “Remember This Decision” checkbox to avoid future security prompts.

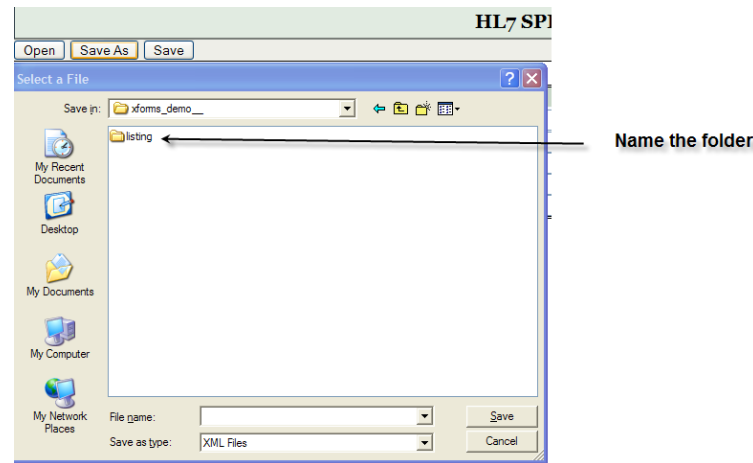
# Creating the Submission Folder



- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the listing SPL file.

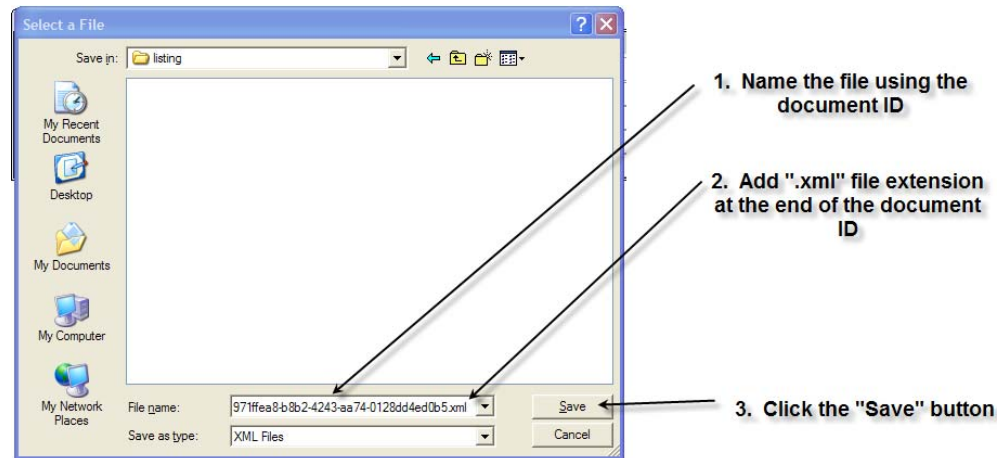


# Naming the Submission Folder



- There is no folder naming convention
- However, we recommend that you not use symbols in the name of the folder.

# Naming the SPL File



- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

# Need More Detailed Instructions?

- Use Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing
- This document is located on the SPL Resources web page:  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

# Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:  
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
  - This validator **NOT** connected to FDA database.
  - This tool assist you in detection of 90 – 95% of technical errors in SPL documents.

# Submitting Files via FDA Gateway

WebTrader Help Logout

## Send document

Select who will receive the document

Gateway: FDATST

Center:  **Select the "OC" center**

## Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path:  **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory:  **Browse...**

Submission type:  **Select "SPL" as the submission type**

## Select a signing certificate

Current file: M:\SPL\_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file:  **Browse...**  
MyCertificate.p12 or MyPrivateKey.pfx

**Send**

# Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph explaining the council's role in coordinating data standards. At the bottom of the main content area is a link for 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

**FDA** U.S. Food and Drug Administration

A-Z Index Search  go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

**For Industry** Email this page Print this page Change Font Size

Home > For Industry > Data Standards

**Data Standards**

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

**FDA Resources for Standards**

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

# SPL-related Technical Assistance/Questions

- SPL e-mail account ([spl@fda.hhs.gov](mailto:spl@fda.hhs.gov))